GP 1616

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION OF:
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Art Unit. 1616

SERIAL NO.: 09/008,957

Examiner: Badio, B.

FILED: January 20, 1998

FOR: 1α-HYDROXYVITAMIN D_5, ITS SYNTHESIS AND USE IN CANCER PREVENTION AND THERAPY

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

RESPONSE TO ELECTION\RESTRICTION REQUIREMENT UNDER 35 U.S.C 121

Sir:

Applicants have carefully studied the Examiner's remarks in the Office Action dated November 19, 1998 and have noted the Examiner's requirement that Applicants elect a single group for prosecution on the merits. In response, Applicants hereby provisionally elect (with traverse) to prosecute the Invention I (as embodied in Claims 1-6 and 10-14).

Applicants respectfully submit, however, that the restriction requirement is improper because Inventions I and III comprise a single inventive concept and are not patentably distinct.

Claims 1-6 and 10-14 are directed to the Vitamin D5 compound ("Invention I"). Claim 7 is directed to the process for making

the compound ("Invention II"), and Claims 8 and 9 are drawn to a method for using the compound in cancer prevention and therapy ("Invention III").

Inventions I and III are related as product and process of use. The inventions are not distinct because, contrary to Examiner's assertion, the process for using the product as claimed cannot be practiced with another materially different product.

The method of Claims 8 and 9 (Invention III) cannot be practiced with another materially different compound because of the unique efficacy of the claimed compound in preventing mammary lesion formation and its lower toxicity. As noted in the specification at page 4, lines 3-6, "preliminary studies in mice indicate 1α-Hydroxyvitamin D_5 is useful in preventing development of carcinogen-induced precancerous lesions at non toxic concentrations." See also Table 2 and discussion thereof on pages 19-20. Furthermore, "1α-Hydroxyvitamin D_5 is less calcemic than a majority of the analogues of vitamin D_3" which allows its possible use in prevention of cancer. Page 4, lines 15-17. See also Table I and discussion thereof on pages 16-17.

1α-Hydroxyvitamin D_5 may also be useful in cancer therapy by inducing the production of TGF-β1, a growth factor compound associated with the inhibition of cancer cell growth. Applicants' studies indicated that the extent of induction of TGF-β1 after treatment with 1α-Hydroxyvitamin D_5 was similar to that observed with the vitamin D_3 analogue, yet 1α-Hydroxyvitamin D_5 was considerably less toxic. Page 25, lines 4-14.

In summary, the claimed compound appears to have the unique ability to prevent the development of carcinogen-induced precancerous lesions (useful in cancer prevention) and induce the production of TGF-β1 (useful in cancer therapy) at non toxic concentrations. Because of this unique ability, the method for preventing the development of precancerous lesions set forth in Claim 8 and the method for treating cancer set forth in Claim 9 using 1α-Hydroxyvitamin D_5 cannot be practiced with another materially different product.

Election of Species

In response to paragraph 6 of the Office Action mailed November 19, 1998, Applicants provisionally elect (with traverse) the species disclosed in Figure 2, R group 13. This is also the species described in Claim 1. Applicants respectfully submit, however, that the election requirement is improper because the species comprising the embodiment of R groups defined by compounds 13a-e are obvious variants.

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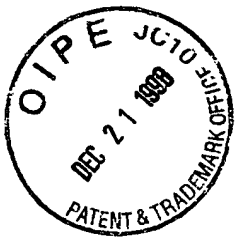
In view of the foregoing, Applicants respectfully request that the restriction requirement vis a vis Invention I and III be withdrawn upon reconsideration and that the election of species requirement vis a vis R groups defined by compounds 13a-e be withdrawn upon reconsideration.

The Examiner is invited to telephone applicant's undersigned attorney if any unresolved matters remain.

Respectfully submitted,



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Dated: 12/17/98

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner Of Patents And Trademarks, Patent And Trademark Office, Washington, D. C. 20231, on December 17, 1998

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